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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/741,531	12/19/2003	Andrew W. Artenstein	3479.1000-001	5148

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HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER

LEWIS, KIM M

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/741,531	Applicant(s) ARTENSTEIN, ANDREW W.	
	Examiner Kim M. Lewis	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
4a) Of the above claim(s) 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 12-19, 22, 24, 25 and 27-37 is/are rejected.
- 7) ☒ Claim(s) 7-11, 20, 23 and 26 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/19/03 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/19/03, 10/15/04</u> | 6) <input type="checkbox"/> Other: <u>Detailed Action</u> |

DETAILED ACTION

Election/Restrictions

The examiner acknowledges applicant's election of species of Group III, claims 1-20 and 22-27 readable thereon.

In response to applicant's request that Groups IV and V be considered together, the examiner contends that these two groups may be considered as one group (*i.e.*, one species.)

Information Disclosure Statement

1. The information disclosure statements filed 12/19/03 and have been received. Note the acknowledged PTO-1449 forms enclosed herewith.
2. The examiner also acknowledges the International Search Report 10/15/04.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 2-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As regards claim 2, it is unclear to the examiner if "at least one widow or region..." is the same as the "at least one section..." in claim 1. From the specification they appear to be one in

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the same, however, they appear to be different structural elements in the claim. Claims 2-4, which depend from claim 2 are consequently unclear.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1, 5-6, 12-19 and 24-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,917,112 ("Kalt").

As regards claims 1, Kalt discloses a universal bandage with transparent dressing, which substantially discloses applicant's claimed invention. More specifically, Kalt discloses a bandaging device for sequestering a wound or inoculation site (Abstract) on a patient in need thereof, comprising a single piece body having no joints (frame 140, the body being integrally formed to encase the wound or inoculation site, the formed body having a substantially transparent top portion (18) for visually inspecting the wound or inoculation site. As can be seen from Fig. 1, the body includes a side portion descending from the top portion to a lower edge, and a flange extending outwardly from the lower edge, the bandaging device being formed from a material that is substantially liquid-impermeable to prevent liquid or other contaminants from reaching the wound or inoculation site (Abstract and col. 4, lines 18-58). Kalt further discloses that the bandaging device also including at least one section (18) that is formed from a material that is substantially liquid-impermeable and vapor-permeable to allow vapor to reach the wound or inoculation site while preventing liquid or other contaminants from contacting therewith.

Kalt fails to teach that the flange extends radially outward from the lower edge. However, a circular bandage meets this limitation, and in various other embodiments Kalt discloses circular bandages. It would have been obvious to one having ordinary skill in the art at the time the invention was made to change the shape of the bandage of the embodiment of Figs. 1 and 2, since it has been held that a change in shape of a prior art device is a design consideration within the level of ordinary skill in the art. *In re Rose*, 220 F.2d 450, 105 USPQ 237 (CCPA 1955).

As regards claim 2, note membrane (18), which forms the window.

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As regards claims 3-4, Kalt discloses the use of TegadermTM, which is a thin polyurethane film. Kalt fails to teach the use of either polypropylene or spunbonded polypropylene. Absent a critical teaching and/or a showing of unexpected results derived from the use of polypropylene or spunbonded polypropylene as the material for the window, the examiner contends that the use of polypropylene or spunbonded polypropylene is an obvious design choice which does not patentably distinguish applicant's invention. Additionally, the examiner wishes the applicant to note that TegadermTM is substantially liquid-impermeable and vapor-permeable and would perform equally as well as polypropylene or spunbonded polypropylene.

As regards claim 5, note the medical grade adhesive (15) disclosed at col. 4, lines 59-63.

As regards claim 6, note liner (16).

As regards claims 12, Kalt discloses at col. 7, lines 29-36 that the device can act as an effective barrier when medicaments are added to the wound. Kalt fails to teach that the medicaments are antibacterials, however, the examiner contends that it would have been *prima facie* obvious to one having ordinary skill in the art to add any type of medicament to the wound, including antibacterials, as long as they assist in wound healing. Kalt additionally fails to teach that the medicament is added to the interior surface of the side portions. The examiner contends that once the medicament is added to the wound it may creep to the interior surface of the side portions. Furthermore, the placement of medicaments on wound dressings is well known in the art and since wound dressings have been used as reservoirs to hold medicaments prior to application to skin of a user, one having ordinary skill in the art would have found it an obvious

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design choice to place the medicament directly on the wound or on the device for application to the wound site.

Regarding claim 13, as can be seen from Fig. 2 of Kalt, the side portion extends perpendicularly away from the skin of the patient when the bandaging device is disposed thereon (note the attached Exhibit).

Regarding claim 14, the flange extends perpendicularly away from the side portion (note the attached Exhibit).

As regards claim 15, Kalt discloses the use of MicrofoamTM as the material of construction for the body. Kalt fails to teach that MicrofoamTM comprises polyester, polyethylene terephthalate glycol, styrene, polyvinyl chloride or a combination thereof. It would have been obvious to one having ordinary skill in the art to select any of claimed materials since it has been held that the selection of a known material based upon its suitability for the intended use is a design consideration within the level of ordinary skill in the art. *In re Leshin*, 227 F. 2d 197, 125 USPQ 416 (CCPA 1960).

As regards claim 16, Kalt discloses in the Abstract sealing (encasing) a wound.

As regards claims 17, the flange of Kalt is capable of attaching to a bandaging material that is affixable to the skin of the patient.

As regards claim 18, note adhesive (15).

As regards claim 19, Kalt fails to teach the bandaging material includes polyester, polyethylene or a combination thereof. Absent a critical teaching and/or showing of unexpected results derived from the use of polyester, polyethylene or a combination thereof as a material of

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construction for the bandaging material, the examiner contends that the material is an obvious design choice which does not patentably distinguish applicant's invention.

As regards claim 22, Kalt fails to teach that the underside of the flange is attached to the material that is substantially liquid-impermeable and vapor-permeable.

As regards claim 24, note the rejection of claim 1 above. In further regard to claim 24, Kalt fails to explicitly teach that that frame is vapor impermeable. However, since Kalt discloses that portion 14 is water-resistant to keep out bacteria and liquids, the examiner contends that it would have been obvious to one having ordinary skill in the art to select a material that is both liquid impermeable and vapor impermeable to prevent any contaminants from entering to the wound site from portion 14.

Regarding claim 25, note the rejection of claim 17 above.

Regarding claim 26, note adhesive (15).

As regards claim 27, note the rejection of claim 12 above.

As regards claim 28, the claimed method is inherently practiced by mere use of the modified device of claim 1.

As regards claim 29, note the rejection of claim 12 above.

As regards claim 30, the device is configured to encase (seal) wounds.

As regards claim 31, Kalt fail to teach the device is placed on a small pox inoculation site. However, the examiner contends that once the skin of a patient is pierced for an inoculation, a wound forms. As such, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place the device of Kalt on any inoculation site,

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including a small pox inoculation site since the inoculation site is a wound and the device of Kalt is for use on wounds.

As regards claim 32, note (18).

As regards claim 33, Kalt fails to teach a notch in the flange to facilitate bending. Kalt, however, was concerned with a bendable/flexible flange since he constructed portion (14) from a stretchable foam. However, the examiner contends that the inclusion of an notch into portion (14) would have been *prima facie* obvious to one having ordinary skill in the art since notches are commonly known and used in the art to allow a sheet of material to contour the body. Also, the addition of a notch to portion (14) of Kalt will assist in further bending/flexible of portion (14), thereby allowing the device to be used on a joint with a lot of motion (*e.g.*, knee or elbow).

9. Claims 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kalt in view of U.S. Patent No. 6,274,787 ("Downing").

10. As regards to claim 34, as can be read from claim 1 above, Kalt discloses substantially all features of the claim. Kalt fails to teach that the body (portion 14) is at least partially arcuate. Downing, however, discloses a transparent, span-over-the-wound bandage, which comprises a body having an arcuate portion (80) from a top portion to a lower edge (Fig. 10) for the purpose of spanning over a wound so as to prevent contact with the wound.

In view of Downing, it would have been obvious to one having ordinary skill in the art the time the invention was made to construct portion (18) of the device of Kalt with an arc in order to prevent contact with the wound of a user.

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As regards claim 35, portion (18) is a window that allows vapor (vapor permeable) to pass therethrough, but is liquid-impermeable.

As regards claim 36, the device of Kalt is for a wound.

As regards claim 37, the modified device of Kalt has a body that is at least partially semi-hemispherical.

Allowable Subject Matter

11. Claims 7-11, 20, 23 and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 6,110,197 issued to Augustine et al. disclose a flexible non-contact wound treatment device with a single joint.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-4796. The examiner can normally be reached on Mondays to Thursdays from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett, can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kim M. Lewis
Primary Examiner
Art Unit 3743

kml
May 31, 2005

Henry Bennett
Supervisory Patent Examiner
Group 3700

Exhibit

U.S. Patent

Apr. 17, 1990

Sheet 1 of 2

4,917,112

FIG. 2

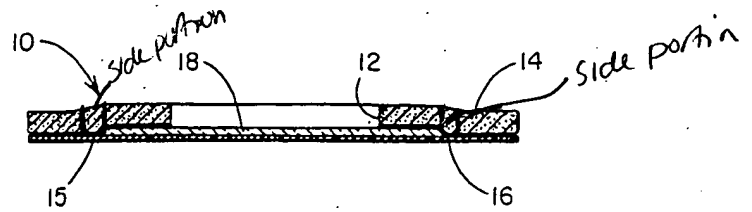


FIG. 1

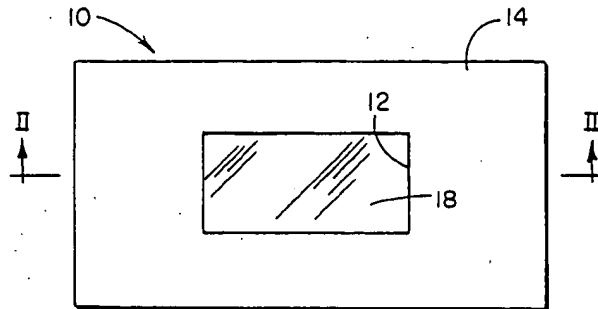


FIG. 3

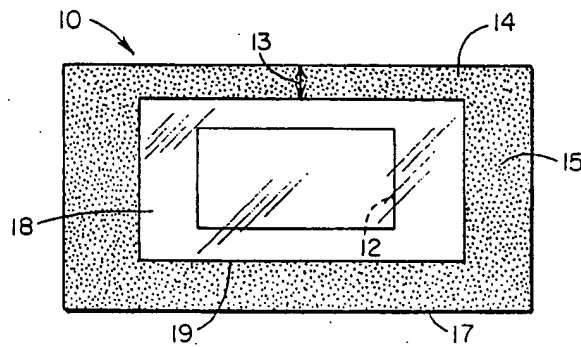


FIG. 4

